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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,760	12/21/2000	Richard Glynn	18547-046600US	4702

7590 02/26/2002

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1627

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/747,760

Applicant(s)
Mack et al

Examiner
Padmashri Ponnaluri

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. Claims 1-21 are currently pending in this application.

Please Note: In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Ph.D., Supervisory Patent Examiner at jyothsna.venkat@uspto.gov or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, drawn to a method of screening a drug candidates comprising;
providing a cell that expresses **an expression profile gene**, classified in class 435, subclass 6.
 - II. Claims 3-11, drawn to a method of screening drug candidates comprising
providing a cell that expresses **an expression profile gene set**, classified in class 435, subclass 6.

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- III. Claims 12-15, drawn to a method of screening for a bioactive agent capable of binding to a B lymphocyte modulator protein (BLMP), classified in class 436, subclass 501.
- IV. Claims 16-18, drawn to a method of evaluating the effect of an immunosuppressive drug (**in vivo**), classified in class 435, subclass 63.
- V. Claims 19-21, drawn to an array of probes, classified in class 436, subclass 518 or class 536, subclass 23.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I-IV are drawn to different methods. These methods have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group I-III are drawn to **in vitro** method of screening a drug candidate, which are different from each other (group I method uses a cell that expresses an expression profile of a single gene; group II method uses a cell that expresses an expression profile of gene set; and group III method uses BLMP protein) . Group IV method is drawn to **in vivo** screening. Thus restriction between the groups is proper.

4. Inventions of groups I-IV and group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inventions of group V are drawn to an array

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(product), which can be used in several different methods, i.e., groups I-III. Thus restriction between the groups is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a) if group I is elected, applicants are requested to elect a single species of cell.
- b) if group II is elected, applicants are requested to elect one type of set from the following:
 - i) set comprises **tolerance set**;
 - ii) set comprises **stimulation set**; and if stimulation set is elected, applicants are further requested to elect gene in which the expression is increased; and a gene in which the expression is decreased;
 - iii) set comprises **immunosuppression set** ; and if immunosuppression set is elected, applicants are further requested to elect gene in which the expression is increased; and a gene in which the expression is decreased;
- c) if group IV is elected, applicants are requested to elect a single gene;
- d) if group V is elected, applicants are requested to elect a single gene .

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 12, 14, 16-17, 20-21 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Applicant is required to reply to this restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Any inquiry concerning this communication should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703)308-2439. The fax number for this group is (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

P. Ponnaluri
Patent Examiner
Technology center 1600
Art Unit 1627
25 February 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: **P. Ponnaluri**

ART UNIT: **1627**

SERIAL NUMBER: 09/747,760

FAX/TELECOPIER NUMBER: (703) 308-4315

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

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